Utah Department of Health

Division of Health Care Financing

Expansion of 340B Drug Pricing Programs

Volume 4

Report to

The Utah Legislature's
Health and Human Services Interim Committee
and
Health and Human Services Appropriations Subcommittee

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I. H.B. 74 –Expansion of State Medicaid 340B Drug pricing program

The 2008 Legislature directed the State Medicaid agency to expand the program's use of savings under the 340B drug pricing program. Specifically, the Department of Health shall determine:

- The feasibility of developing and implementing one or more 340B pricing programs for a specific disease, similar to the hemophilia disease management program;
- Whether the 340B program results in greater savings for the department than other drug management programs for the particular disease. The Department shall report regarding:
    - Potential cost savings to the Medicaid program from the expansion of use of the 340B program;
    - Amendments and waivers necessary to implement increased use of 340B pricing;
    - Projected implementation of 340B pricing programs;
- The Department shall work with the Association for Utah Community Health to identify and assist community clinics that do not have 340B drug pricing programs to determine whether:
    - Patients of the Community Health Center would benefit from establishing a 340B drug pricing program on site or through a contract pharmacy;
    - The Community Health Center can provide 340B drug price savings to the Health Center's Medicaid patients

<u>Feasibility</u>

In previous reports, the Division has described the feasibility of expanding Utah's current 340B Disease Management program to include the management of additional disease states. The Centers for Medicare and Medicaid Services (CMS) indicate that expansion of this program is subject to approval of a new Freedom of Choice 1915(b) waiver and additional State Plan Amendments.

CMS regional office representatives state that obtaining their approval remains a possibility. They have indicated that, once a new Freedom of Choice waiver is approved, each additional disease state will require a State Plan Amendment.

Potential Cost Savings

In previous reports potential savings have been calculated. These savings will only be possible should CMS provide the required approvals. Since the initial calculation of potential savings, the Medicaid program has changed reimbursement rates through the expansion of the Utah Maximum Allowable Cost program. Changes in reimbursement rates are also being planned for brand name medications. As budgets are finalized for 2009 and 2010, these reimbursement rate changes will lower previously estimated savings available through the expansion of the 340B drug Disease Management program.

340B pricing information is not accessible to Medicaid. Cost savings have been calculated based on estimated 340B prices. Bill Von Oehson, president and general counsel of "The 340B Coalition," a national organization of safety net DSH hospitals based in Washington D.C. maintains that 340B prices are on average AWP minus 49 percent. The actual price varies by drug product. There is no question that potential cost savings exist. Those savings are not always attainable given the constraints of the system, such as 340B requirements, CMS approvals, and availability of willing contractors.

Necessary Amendments and Waivers

As Utah Medicaid seeks to expand its disease management approach to 340B savings, a new freedom of choice waiver is required because access to the 340B purchased drugs must be restricted to a single 340B covered entity. Otherwise, clients can access medications at any Medicaid participating pharmacy, including non-340B pharmacies. This would result in a corresponding loss of potential savings.

In recent conversations with CMS representatives in the Denver Regional Office, the Division has learned that a new State Plan Amendment (SPA) is required for the expansion of disease management programs in Utah. It was hoped that one general State Plan Amendment for Disease State Management would suffice, but CMS has indicated that this is not acceptable. A new amendment for each specific disease state will have to be approved by CMS before an expansion can occur. On-going meetings with CMS are being conducted to continue to identify all needed approvals.

A draft SPA has been submitted to CMS for review and comment. Division staff is currently working on the reimbursement rate methodologies that are associated with individual disease states. The Department currently awaits additional comments and suggestions on this draft SPA from CMS officials. Draft waiver language is also under construction for CMS submission, as well.

Another state plan amendment may be required for outpatient hospital clinics to bill for 340B drugs. Additional programming is needed to support billing and reimbursement at 340B prices for pharmaceutical products currently billed using Health Care Procedure Coding System's (HCPCS) codes. Technical staff is reviewing our system to determine what is needed to support this billing process. Provider input has been sought to assure billing can be supported by the providers.

Projected implementation of 340B programs

Because of the Deficit Reduction Act of 2005, Medicaid is required to pursue manufacturer rebates on drugs administered in a physician's office. This impacts 340B covered entities because rebates cannot be sought from manufacturers for 340B purchased drugs. Claims system programming must be able to accommodate both the 340B requirements and the rebate program needs. These changes have been requested and are being prioritized for programming.

The programming changes will make it possible to implement a savings program that requires all 340B covered entities to fill and bill with 340B purchased drugs for all Medicaid clients of the covered entity. Implementation of this program is currently scheduled for June 1, 2009. This revised date is a result of additional information on 340B billing requirements received from CMS in February 2009. Medicaid cannot require National Drug Code (NDC) information for 340B drug claims billed by Outpatient Hospital Clinics. It also may be delayed further depending on the programming requirements needed to implement bills passed in the 2009 Utah State Legislature.

The Division has been meeting on an on-going basis with hospital providers to develop the needed solutions to the current billing process to allow them to submit 340B prices. At first providers thought that this would cause problems with Medicare cost reporting. Further investigation reveals that there are ways to bill 340B prices and satisfy Medicare cost reporting requirements, and programming needs are being identified for Medicaid and provider's systems.

Provider notification and education is scheduled to take place through a Medicaid Information Bulletin (MIB) article as well as a letter addressed to all outpatient covered entities. Identifying 340B covered entities remains difficult. The Office of Pharmacy Affairs provides a list of these entities, but this list does not match with the Medicaid provider file making the task complicated and cumbersome. A letter has been established and notification is currently scheduled for June 1, 2009.

Freedom of Choice waivers with disease management programs can take a year to 18 months to get approved. Such was the case with the original Hemophilia program. Depending on the disease state and number of patients involved, implementation can take an additional six to seven months. Refer to Table 1 below for a listing of specific implementation tasks for the Multiple Sclerosis program expansion. Initial estimates for start and finish dates will have to be revised from report to report as implementation issues arise and requirement changes are received from CMS. The most recent issue has been the requirement from CMS that the prototype program already in existence receive a full review. The Division of Health Care Financing is researching and providing reports to CMS on the existing program for Hemophilia clients, as requested.

Required program changes and annual budget activities have caused some delays in the program. In response to budget short falls, Medicaid staff was directed to expand the current Maximum Allowable Cost (MAC) program. This was prioritized above the 340B Program Expansion as the Medicaid budget had been reduced by the amount of the projected MAC savings.

TABLE 1. – 340B Program Expansion Projected Implementation Plan

Task #	Description	Estimated Duration	Start Date	Finish Date	% Complete
1	Programming changes to capture claims data in Point-of-Sale claims.	5 months	01/25/08	07/01/08	100%
2	Programming changes to capture physician administered drug claims data.	2 months	11/01/08	06/01/09	90%
3	Provider notification and education	6 months	07/01/08	06/01/09	20%
4	Multiple Sclerosis claims information capture	3 months	01/01/09	06/01/09	0%
5	Analysis of Multiple Sclerosis 340B Report and staff recommendation on feasibility	15 days	06/01/09	06/15/09	0%
6	Write New Freedom of Choice Waiver	2 months	06/15/09	8/15/09	0%
7	Waiver Review and Approval by CMS	18 months	8/15/09	2/15/11	0%
8	Write State Plan Amendment (SPA)	15 days	02/15/11	03/01/11	0%
9	SPA Review and Approval by CMS	18 months	03/01/11	09/01/12	0%
10	RFP Development/Approval/Analysis	3 months	09/01/12	12/01/12	0%
11	Contract Award/Negotiations	2 months	12/01/12	02/01/13	0%
12	Provider/Client Notification	2 months	02/01/13	04/01/13	0%
13	**Functional Multiple Sclerosis 340B Management Program**	Contracted year	04/01/13	03/31/14	0%

Association for Utah Community Health

The Association for Utah Community Health (AUCH) is an organization of 340B community health centers, federally qualified health centers, family planning clinics, and local health departments. There are 29 covered entities in the AUCH organization. AUCH covered entities charge only the cost of the 340B drugs plus a dollar, providing a great benefit to their patients. Medicaid patients are insensitive as to whether or not 340B purchased drugs are used since the co-pay for them is the same.

A 340B covered entity by definition buys 340B drugs for use in the facility. All covered entities provide 340B purchased medications, at least in the physicians' offices, whether or not pharmacy services are available on site or through a contracted pharmacy. All of the AUCH members have on site pharmacies or have a contracted pharmacy. All covered entities can elect whether or not they will choose to fill and bill with 340B purchased drugs for their Medicaid patients. Medicaid is currently working on

programming needs to make billing for 340B easier. AUCH has indicated to Medicaid that AUCH member covered entities will fully participate.

II. Conclusion

The 340B drug purchasing program is a program of the Health Resources Services Administration (HRSA), and is administered by the Office of Pharmacy Affairs. The entire program is governed by rules and regulations external to CMS and the Medicaid Agency. Because the 340B program impacts the Medicaid drug rebate program, both have requirements that must be met for access to 340B drug savings.

III. Recommendation

Because of the difficulty and expense associated with program design and CMS approval, disease management programs, under freedom of choice waivers, should be limited to specific disease states treated with expensive medications. This will help assure potential cost savings exceed administrative implementation expense.

The greatest opportunity for Medicaid to take advantage of 340B savings is to require 340B covered entities to fill and bill all drugs administered by the physician and prescriptions for Medicaid patients of the covered entity, with 340B purchased drugs. Pursuit of this option predates H.B. 74, but was delayed pending this legislation. Beginning June 1, 2009 Utah Medicaid plans to mail out instructions to all state 340B covered entities advising them that this is now a requirement. Consideration for legislation during the 2009 Utah General Session mandating 340B entities bill 340B prices would greatly assist in realizing the maximum potential savings.